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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/814,689

03/31/2004

Anthony D. Cristillo

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07/22/2009

REED SMITH, LLP

ATTN: PATENT RECORDS DEPARTMENT

599 LEXINGTON AVENUE, 29TH FLOOR

NEW YORK, NY 10022-7650

EXAMINER

HUMPHREY, LOUISE WANG ZHIYING

ART UNIT

PAPER NUMBER

1648

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/814,689	<b>Applicant(s)</b> CRISTILLO ET AL.	
	<b>Examiner</b> LOUISE HUMPHREY	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13-16, 21-24 and 29-38 is/are pending in the application.
- 4a) Of the above claim(s) 13-16 and 21-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04 June 2009 has been entered.

**DETAILED ACTION**

This Office Action is in response to the amendment filed 4 June 2009. Claims 1-12, 17-20, and 25-28 have been cancelled. Claims 13-16, 21-24, and 29-38 are pending. Claims 13-16 and 21-24 are drawn to a nonelected subject matter and hence are withdrawn from further consideration pursuant to 37 CFR 1.142(b).

Claims 29-38 are currently examined.

***Specification***

The abstract of the disclosure is objected to because there is a discrepancy in SEQ ID NO: designation on page 3 in paragraph [0005], in line 10-11, "PSAP (SEQ ID NO:3)" should be PSAP (SEQ ID NO:4) and "YXXL (SEQ ID NO:4)" should be YXXL (SEQ ID NO:3).

Correction is required. See MPEP § 608.01(b).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 29-33 under 35 U.S.C. §102(b) as being anticipated by González *et al.* (1999, hereinafter “González”) is **maintained** for reasons of record.

The instant claims are directed to a DNA molecule comprising a nucleic acid encoding a viral protein comprising one deletion of the contiguous amino acids consisting of the sequence selected from the group consisting of PTAP (SEQ ID NO:1), PPX<sub>1</sub>Y (SEQ ID NO:2), YX<sub>2</sub>X<sub>3</sub>L (SEQ ID NO:3), and a combination thereof.

González teaches a plasmid comprising a nucleic acid comprising a mutation of the SIV Gag coding gene, which is a deletion of the C-terminus contiguous amino acids VETGTADKHPATSRPTAP, comprising a deletion of the budding mediating motif consisting of PTAP, according to Figure 1. The deletion mutant nucleic acid is introduced into a vector also comprising the coding sequence for the SIV protease. See page 6385, left column and Figure 1. Thus, the instant invention is anticipated by González *et al.*

***Response to Arguments***

Applicant's arguments filed 04 June 2009 have been fully considered but they are not persuasive. Applicant argues that González fails to disclose the deletion of a contiguous deletion consisting of any of the above three amino acid sequences or a combination thereof.

Applicant's principal argument here that the claims contain the closed-ended transition term "consists," and that the term narrows the entire claim, is unpersuasive. Examiner respectfully disagrees with Applicant's interpretation of the claim limitations. The closed limitation "consists of" is preceded by open limitation "comprising" in the claim limitation. The reasonable interpretation of the claims containing both of the terms "comprising" and "consists" is that the term "consists" limits the "said portion" language to the subsequently recited peptides, but the earlier term "comprising" means that the claim can include that portion plus other peptides. Read in context, the claims thus do not preclude a protein sequence having additional mutations. Therefore, the instant claims permit additional mutations on either side of the recited "contiguous deletion consists of an amino acid sequence selected from the group consisting of PTAP (SEQ ID NO:1), PPX<sub>1</sub>Y (SEQ ID NO:2), YX<sub>2</sub>X<sub>3</sub>L (SEQ ID NO:3), and a combination thereof." See MPEP 2111.03. When the phrase "consists of" appears in a clause of the body of a claim, rather than immediately following the preamble, it limits only the element set forth in that clause; other elements are not excluded from the claim as a whole. *Mannesmann Demag Corp. v. Engineered Metal Products Co.*, 793 F.2d 1279, 230 USPQ 45 (Fed. Cir. 1986). >See also *In re Crish*, 393 F.3d 1253, 73 USPQ2d 1364 (Fed. Cir. 2004) (The claims at issue "related to purified DNA molecules having

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promoter activity for the human involucrin gene (hINV).” *Id.*, 73 USPQ2d at 1365. In determining the scope of applicant’s claims directed to “a purified oligonucleotide comprising at least a portion of the nucleotide sequence of SEQ ID NO:1 wherein said portion consists of the nucleotide sequence from ... to 2473 of SEQ ID NO:1, and wherein said portion of the nucleotide sequence of SEQ ID NO:1 has promoter activity,” the court stated that the use of “consists” in the body of the claims did not limit the open-ended “comprising” language in the claims (emphases added). *Id.* At 1257, 73 USPQ2d at 1367. The court held that the claimed promoter sequence designated as SEQ ID NO:1 was obtained by sequencing the same prior art plasmid and was therefore anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. *Id.* at 1256 and 1259, 73 USPQ2d at 1366 and 1369. The court affirmed the Board’s interpretation that the transition phrase “consists” did not limit the claims to only the recited numbered nucleotide sequences of SEQ ID NO:1 and that “the transition language comprising” allowed the claims to cover the entire involucrin gene plus other portions of the plasmid, as long as the gene contained the specific portions of SEQ ID NO:1 recited by the claim[s]” *Id.* at 1256, 73 USPQ2d at 1366.<

The rejection of claims 29-33 under 35 U.S.C. §102(b) as being anticipated by Puffer *et al.* is **maintained** for the same reasons as set forth above.

The rejection of claims 34-38 under 35 U.S.C. §102(b) as being anticipated by Puffer *et al.* is **withdrawn** in view of the claim amendment.

### ***Response to Arguments***

Applicant's arguments with respect to claim 34-38 have been considered but are moot in view of the new ground of rejection.

### **NEW REJECTION**

Claims 29-38 are rejected under 35 U.S.C. §102(b) as being anticipated by Licata *et al.* (February 2003).

The instant claims are directed to a DNA molecule comprising a nucleic acid encoding a viral protein comprising a deletion mutation of the budding mediating motif that comprises or consists of an amino acid sequence selected from the group consisting of PPX<sub>1</sub>Y (SEQ ID NO:2), YX<sub>2</sub>X<sub>3</sub>L (SEQ ID NO:3), and a combination thereof;

wherein X<sub>1</sub> is not P;

wherein when X<sub>2</sub> is P, X<sub>3</sub> is not D; and

wherein when X<sub>3</sub> is D, X<sub>2</sub> is not P;

a vector comprising the DNA molecule; and a composition comprising either the DNA molecule or the vector.

Licata *et al.* teaches Ebola virus VP40 protein expression plasmids comprising a deletion of the viral budding motif PTAP or PTAPPEY, which is an overlap of the PTAP motif and the PPX<sub>1</sub>Y motif in the instant claims. See Figure 1. Thus, the instant invention is anticipated by Licata *et al.*

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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/L. H./  
Examiner, Art Unit 1648

/Jeffrey S. Parkin/  
Primary Examiner, Art Unit 1648

7 July 2009